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STATE OF DELAWARE DEPARTMENT OF STATE

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DIVISION OF PROFESSIONAL REGULATION

PUBLIC MEETING NOTICE: BOARD OF PHARMACY

DATE AND TIME: Wednesday, September 18, 2013

PLACE: Conference Room A, Cannon Building

861 Silver Lake Blvd., Dover, DE 19904

APPROVED: October 16, 2013

MEMBERS PRESENT

Joli Martini, R.Ph., PharmD, Professional Member, President Howard Simon, R.Ph, Professional Member Sandra Zaragoza, R.Ph, Professional Member Bonnie Wallner, R.Ph, Professional Member Kenneth Sellers, Public Member Matthew Maher, Public Member David W. Dryden, R.Ph., J.D., Executive Secretary Jay Galloway, Public Member

MEMBERS ABSENT

Kimberly Robbins, R.Ph, Professional Member, Vice President

DIVISION STAFF/DEPUTY ATTORNEY GENERAL PRESENT

Eileen Kelly, Deputy Attorney General Theresa Newman, Administrative Specialist II Alicia Kluger, Pharmacist Compliance Officer

ALSO PRESENT

Suzanne Raab-Long
Sandra Robinson
Cheryl Heiks
Ujjwala Shenoy
Kevin Morgan
Jaime Fring
Tammy Liu
Dierdre Mallika
Stelios Chrisopoules
Jessica Dugan
Kristy Henderson
Jerrie Chiquore
Ashley Webb
Jeremiah Hicks

Brenda Pavix

Janos Levif Kevin Musto

Rina Kelley

CALL TO ORDER

Ms. Martini called the meeting to order at 9:33a.m.

REVIEW OF MINUTES

A motion was made by Mr. Simon, seconded by Ms. Maher, to approve the meeting minutes of August 21, 2013 as amended. The motion unanimously carried.

PRESIDENT'S REPORT

Ms. Martini advised there was no quorum for the Controlled Substance Committee meeting that was scheduled for August 27, 2013. Two new members were introduced to the Board, Kenneth Sellers who is serving as a public member and Bonnie Wallner, serving as a professional member. Ms. Martini gave kudos to Sandra Robinson for her years of service to the Board.

UNFINISHED BUSINESS

Complaint Status

- 13-03-11 Assigned to Hearing Officer
- 13-09-11 Assigned to Hearing Officer
- 13-12-11 Forwarded to Office of Attorney General
- 13-19-11 Forwarded to Office of Attorney General
- 13-07-12 Assigned
- 13-09-12 Assigned
- 13-01-13 Forwarded to Office of Attorney General
- 13-02-13 Assigned
- 13-03-13 Assigned
- 13-04-13 Forwarded to Office of Attorney General
- 13-05-13 Assigned
- 13-06-13 Forwarded to Office of Attorney General
- 13-07-13 Assigned
- 13-08-13 Assigned
- 13-09-13 Assigned
- 13-11-13 Forwarded to Office of Attorney General
- 13-13-13 Forwarded to Office of Attorney General
- 13-14-13 Assigned
- 13-15-13 Assigned
- 13-16-13 Assigned
- 13-17-13 Assigned
- 13-18-13 Assigned
- 13-19-13 Assigned

Prescription Monitoring Program (PMP) Update

Mr. Dryden advised a DEA task force has been created within the last few months. Data is being requested by the DEA, however it cannot be released because of how the new law is written. There will be a PDAC meeting regarding PMP. The 72 hour law passes pertaining to Methadone Clinics and Veterinarian Clinics.

Mr. Maher circulated an article regarding PMP from CVS Caremark.

Collaborative Practice Review

The Board reviewed House Bill 386 handout which was previously presented years ago and was not accepted. The Board reviewed the House Bill as presented. A motion was made by Mr. Simon, seconded by Ms. Zaragoza to accept the proposed bill as is. The motion unanimously carried. Mr. Dryden will present the bill to other related Boards.

Review of Patient Counseling

Board members reviewed a handout of proposed regulations regarding patient counseling. Mr. Simon suggested to take out "in a confidential manner" under 5.2.4. Ms. Kelly suggested that the Board take out "or a pharmacist's designee" and change it to "intern" or "student".

A motion was made by Mr. Simon, seconded by Mr. Galloway to accept 5.2 Rules and Regulation as amended. The motion unanimously carried.

Review of Pharmaceutical Compounding Regulations

Mr. Dryden advised we were still waiting on the DEA.

Review of Re-Instatement Request

The Board reviewed continued education documents re-submitted by Ujjwala Shenoy. Ms. Shenoy presented her situation before the Board, explaining why she was not compliant in 2012 but has since then completed all make up continuing education to gain compliance to the order. A motion was made by Mr. Simon, seconded by Mr. Galloway to lift the suspension of pharmacy licensure for Ujjawala Shenoy. The motion unanimously carried.

Review and Discussion of Recommendations of Hearing Officer

A motion was made by Mr. Simon, seconded by Ms. Wallner to strike the letter of reprimand to the Recommendation of Hearing Officer for Loren Mays. The motion was approved with the exception of Mr. Maher and Ms. Martini, who opposed.

Discussion of Regulation 12.0 Health Care Facilities

Ms. Kluger and Ms. Robinson will discuss Regulation 12.0 at the next month's meeting. Discussion of Oxygen Bar Ms. Kelly advised that each state has its' own jurisdiction regarding Oxygen Bar. The FDA regulates that the intake of oxygen requires a prescription, if taken for medical purposes. Mr. Dryden will speak with the FDA and Public Health regarding this issue so that they are aware and can give further guidance.

Request from PharmaScript

Mr. Dryden will contact Atlantic Shores Rehabilitation & Nursing Center and advise them of Board question pertaining to the prescriptive items on the list. The Board delegated the responsibility to the President of the Board to inspect Nursing Home Facilities when a request is placed to increase the allowed amount of items of a Control Kit. Ms. Martini accepted the responsibility.

Review and Discussion of Consent Agreement

The Board tabled the Consent Agreement of Michelle Woods, pending a response from the DAG.

NEW BUSINESS

Pharmacist and Intern Licensure Approval Ratifications

A motion was made by Mr. Galloway, seconded by Ms. Zaragoza, to ratify the approval of the Pharmacist applications of Kim Ford, Jennifer Abernathy, Ryan DeLorraine, Shannon Barry, Christine Skrzypiec, Sminat Adekoya, Kaylei DeHart, Rose Marese-Smith, Tamanna Patel, DeAngelo Price, Melanir Olsen, Meredith Miranda, Kristen Campbell, Michael Holbrook, Thuy Le, Hardik Shah, James Appio, Laurel Lindberg, Kareem Karara, Gina Doh, Craig Hughes, Teresa Lee, Raqueeba Hassan, and Shlok Prasad. The motion unanimously carried.

A motion was made by Ms. Robinson, seconded by Mr. Simon to ratify the approval of the Intern Pharmacist application of Tyler Mullen. The motion unanimously carried.

Non-Resident Pharmacy Licensure Approval Ratifications

A motion was made by Mr. Simon, seconded by Ms. Wallner, to ratify the approval of the nonresident pharmacy applications of Precise Compounding Pharmacy Inc., Woodland Hills

Pharmacy, Diamondback Drugs, Rx To You Pharmacy, Inc, and Well Care Discount. The motion unanimously carried.

Wholesale Distributor Licensure Approval Ratifications

A motion was made by Mr. Galloway, seconded by Ms. Zaragoza, to ratify the approval of the wholesale distributor applications of Auxilium Pharmaceuticals Inc., Patterson Veterinary Supply Inc., Cardinal Health, Sonexus health Distribution Services, LLC. The motion unanimously carried.

Retail Pharmacy Licensure Approval Ratification

N/A

Medical Gas Dispensers

A motion was made by Mr. Simon, seconded by Ms. Wallners, to ratify the approval of the Medical Gas Dispenser applications of Royal Medical Supply, First Choice Home Medical Equipment, LLCNew Castle, DE, and First Choice Home Medical Equipment, LLC. - Milford, DE. The motion unanimously carried.

Pharmacist-In-Charge Interviews

A motion was made by Mr. Sellers, seconded by Mr. Simon to add 5.4.3 Deidre Mallika and 5.4.4 Kristy Henderson to the agenda. The motion unanimously carried.

- Mr. Simon conducted a PIC interview for Tammy Liu . She is employed by CVS #3038.
- Mr. Simon conducted a PIC interview for Rina Kelley. She is employed by Cape Pharmacy.
- Mr. Simon conducted a PIC interview for Deidre Mallika. She is employed by CVS #3042.
- Mr. Simon conducted a PIC interview for Kristy Henderson. She is employed by Walgreens #11008.

Review of Application – Eileen Kelly

A motion was made by Mr. Simon, seconded by Mr. Maher to propose to deny the application of Vickburg Special Care Pharmacy and Compounding for the reasoning of having discipline of one of the officers listed on the application. The motion unanimously carried.

Regal Heights in Hockessin Drug List Review

As per the Board's decision, Ms. Martini will conduct an investigation of the pharmacies request and advise of decision.

COMMITTEE REPORTS

Legislative – Sandy Robinson, Howard Simon, Jay Galloway, Kim Robbins and David Dryden

Mr. Dryden presents legislative updates and stated that the next legislative meeting will be held at the Cooper Building on October 2, 2013 at 1pm.

Continuing Education – Joli Martini:

None.

Consumer Affairs – Matthew Maher and Jay Galloway:

None.

Professional Liaisons – Sandra Zaragoza:

Ms. Zaragoza gave a synopsis of the Delaware Pharmacist Society, Board of Directors Meeting that was held on September 17, 2013 and announced dates and times for upcoming DHSP events.

Controlled Substance Liaisons – Howard Simon, Jay Galloway and David Dryden:

Compounding testosterones were stopped from being sent to physicians' offices in which they were then being sent directly to patients. However after issues that were being seen by this process, the DEA agreed that the compounding testosterones should be issued by the physician to the patient.

Ms. Dryden advised that the Controlled Substance Committee meeting was cancelled due to no quorum. The next meeting will be held in October.

COMMITEE UPDATES REGARDING PROPOSED REGULATIONS

USP 795 & 797 Committee – Sandy Robinson, Howard Simon, Alicia Kluger, Brenda Pavlic, Sandra Zaragoza, Hooshang Shanehsaz, Calvin Freedman and David Dryden: None.

Pharmacy Technician Registration Committee – Howard Simon, Matt Maher, Sandy Robinson, Kim Robbins, Kevin Musto, Maryanne Holzapfel and David Dryden: Subcommittee will meet at 11:00 a.m., immediately following the Board meeting.

BOARD CORRESPONDENCE

Mr. Dryden read the letter from the Tennessee Board of Pharmacy. The letter is regarding a survey of Board member duties. Mr. Dryden responded with the Board's objectives section § 2501 of license laws.

EXECUTIVE SECRETARY AND INSPECTION REPORT - David Dryden, Samantha Nettesheim and Alicia Kluger

Mr. Dryden advised they were starting investigations on pain doctors and veterinarian offices to ensure compliance of new legislation, 72 hour dispensing laws. He also stated there is a conflict of regulatory changes with the 72 hour dispensing law that was passed.

Mr. Dryden advises of upcoming meeting he will attend, District 2 meeting in October in Maine, and NASCA meeting Kansas City.

Ms. Kluger reported the following:

The following inspections and activities were completed during the last 30 days:

- 1 Nursing Home inspection
- 1 pharmacy provider and drug audit
- 1 routine pharmacy inspection
- 1 Researcher inspection

There were also multiple drop-ins to evaluate prescription compliance and concerns. Myland Pharmaceuticals reported a loss. The cargo was taken while in transit from Chicago to Orlando.

Mrs. Kluger will attend NABP sponsored Sterile Compounding Inspection Training in Chicago on October 9th and 10th 2013.

NEWSLETTER UPDATES

None.

OTHER BUSINESS BEFORE THE BOARD

Ms. Kelly suggested making a bill in regards to Rules and Regulations 8.3, qualifications for getting a permit for wholesale distributor.

PUBLIC COMMENTS

Kevin Musto elaborates on upcoming DPS and DEA take back event.

NEXT SCHEDULED MEETING

The next meeting is scheduled for October 16, 2013

ADJOURNMENT

There being no other business before the Board, a motion was made by Mr. Simon, seconded by Mr. Maher, to adjourn the meeting. The meeting was adjourned at 11:35am.

Respectfully submitted,

Theresa Newman

Administrative Specialist II

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